MAR 1 2 2002

K013109

510(K) SUMMARY

1. HAKKO SHOJI CO., LTD
7-9 Kamimeguro 1-Chome, Meguro-ku
Tokyo 153 Japan
81-(3)-464-8500 Fax 81-(3)-464-8539

Contact person: M. Moruyama

2. DEVICE NAME
Proprietary Name(s): SONOPSY
Common Name(s): Aspiration biopsy needle

Classification:
Aspiration biopsy needle (gastroenterology-urology biopsy instrument).
21CFR 876.1075 Class II
Product Code: FCG

3. STATEMENT OF SUBSTANTIAL EQUIVALENCE:

Predicate Device:

INRAD/MANAM	Accucore Biopsy Needle	K981166
E-Z-EM, INC.	Lufkin Aspiration Needle	K882601
DAUM Corp.	DAUM AspirationNeedle	K974575

The Sonopsy Aspiration Biopsy Needle is substantially equivalent to the referenced predicated devices in that it is similar with respect to technological characteristics and intended use.

4. DESCRIPTION OF THE DEVICE(S):
Needle size: 14G to 21G, 80 to 200mm
Needle tip: Biopsy point
Inner needle tip: pencil point or trocar point
Suction syringe: 7 ml
Plunger slide: 35 mm
Guide needle size: L=50 to 80 mm or without
Guide needle tip: Lancet point or blunt end
Filter paper: size 20x35mm, 3 pieces

Product Code No.	Needle size	Needle tip	Inner needle tip	Syringe	Guide needle size	Guide needle tip	Filter paper
22032170	21Gx170mm	Biopsy point	Pencil point	7 ml	18Gx70mm	Lancet point	20x35 3 pieces
22032180	21Gx180mm	Biopsy point	Pencil point	7 ml	18Gx70mm	Lancet point	20x35 3 pieces

5. STATEMENT OF INDENDED USE
The Sonopsy aspiration needle is intended to percutaneously obtain abdominal tissue including the liver, prostate, kidney, breast, lymph node, and other soft tissues using ultrasonic visualization.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 12 2002

Mr. Shiro Kitagawa
Director, Marketing Division
Hakko Shoji Co., Ltd.
7-9 Kamimeguro 1-Chome,
Meguro-ku,
Tokyo 153 JAPAN

Re: K013109
Trade/Device Name: HAKKO Sonopsy Biopsy Needle Set
Regulation Number: 21 CFR §876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: 78 FCG
Dated: December 21, 2001
Received: December 26, 2001

Dear Mr. Kitagawa

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

~~K013710~~

K013109

510(k)NUMBER (IF KNOWN) K013109

DEVICE NAME: Aspiration Biopsy Needle

INDICATION FOR USE:

The Sonopsy aspiration needle is intended to percutaneously obtain abdominal tissue including the liver prostate, kidney, breast, lymph node, and other soft tissues using ultrasonic visualization.

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013109

(please do not write below this line-continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √ OR Over-The-Counter-Use
(Per 21 CFE 801.109) (Options Format 1-2-9